of 0.34 mg/kg/week; and showed a median height of 110.0cms (-2.5 SDS (Tanner)) at baseline. Likewise, girls reached a median height of 117.1cms (-1.9 SDS (Tanner)) at the end of the first year and 122.5cms (-1.6 SDS (Tanner)) at the end of the second year; which represents an improvement of over 20% growth compared to girls with TS without GH therapy. **CONCLUSIONS:** Due to an earlier initiation of treatment in Colombian girls compared to global reported data (at 9.7 years), GH achieved at the end of first year height increments of 8.6cm for the Colombian cohort vsersus 7.2cm in global cohort.

PDB14

ASSESSING TREATMENT SUCCESS OF DIABETES THERAPIES - NUMBER NEEDED TO TREAT TO REACH A CLINICALLY RELEVANT COMPOSITE ENDPOINT: USING A META-ANALYSIS OF THE LIRAGLUTIDE CLINICAL TRIAL PROGRAM

Langer J[1], Bouchard JR[1], Ploug UJ[2]
[1]*Novo Nordisk, Inc., Princeton, NJ, USA,* [2]*Novo Nordisk A/S, Søborg, Denmark*

OBJECTIVES: The ADA/EASD Consensus Panel recommends an individualized treatment approach for patients with type 2 diabetes (T2DM) based on efficacy, safety, tolerability, and ease of use. A challenge in the management of T2DM is to maximize glycemic control while minimizing side effects, such as weight gain and hypoglycemia. A clinically relevant composite endpoint of HbA1c<7%, no weight gain, and no hypoglycemia may be useful for evaluation of diabetes treatments. The objective is to estimate the Number Needed to Treat (NNT), using this composite endpoint, across all seven RCTs in T2DM patients in the liraglutide clinical trial program. **METHODS:** The findings of a recently conducted meta-analysis (Zinman et al. 2012) from seven trials (N=4625) at week 26 in the liraglutide clinical trial program were used to calculate the NNT to achieve the composite endpoint of HbA1c<7%, no weight gain and no hypoglycemia for liraglutide vs. comparator therapies and placebo. Logistic regression on the intent-to-treat population using the last observation carried forward was used. The NNT was calculated as 1/Absolute Risk Reduction (ARR), with ARR being the difference in the percentage of patients achieving the composite endpoint with liraglutide vs. the comparator therapy or placebo. **RESULTS:** The calculated NNT values for liraglutide 1.2 mg ranged from 3.8 (vs. rosiglitazone) to 4.8 (vs. sitagliptin) and from 2.9 (vs. rosiglitazone) to 6.7 (vs. exenatide) for liraglutide 1.8 mg. The NNT across all comparators for liraglutide 1.2 mg was 3.8 vs. rosiglitazone, 4.2 vs. glimepiride, 4.2 vs. placebo and 4.8 vs. sitagliptin. For liraglutide 1.8 mg the NNT was 2.9 vs. rosiglitazone, 3.1 vs. glimepiride, 3.1 vs. placebo, 3.4 vs. sitagliptin, 4.0 vs. insulin glargine and 6.7 vs. exenatide. **CONCLUSIONS:** Across the seven phase 3 trials in the liraglutide clinical trial program, the calculated NNT suggests that liraglutide provides clinically meaningful benefits in T2DM.

PDB15

INITIATION OF INSULIN OCCURRED MORE FREQUENTLY AND EARLIER IN OLDER PATIENTS WITH TYPE 2 DIABETES TREATED WITH INITIAL SULFONYLUREA MONOTHERAPY THAN WITH METFORMIN

Qiu Y[1], Fu AZ[2], Davies MJ[1], Engel SS[3]
[1]*Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA,* [2]*Georgetown University, Washington, DC, DC, USA,* [3]*Merck Sharp & Dohme Corp., Rahway, NJ, USA*

OBJECTIVES: The present study examined the association between initial monotherapy with metformin (MET) or sulfonylurea (SU) and subsequent initiation of insulin in older patients with type 2 diabetes mellitus (T2DM). **METHODS:** In a retrospective cohort study using the GE electronic medical database, eligible patients with T2DM included those ≥65 yrs who received their first prescription (Rx) of SU or MET as initial monotherapy between 2003 and 2008. The follow up lasted to the end of 2009 or the patient's latest data available. Insulin initiation was determined by Rx records. Logistic regression analysis evaluated the likelihood of insulin addition and Cox regression model estimated time to initiation of insulin. Differences in baseline characteristics (demographics, clinical and lab measures, and comorbidities) were controlled for using propensity score matching (PSM). **RESULTS:** Overall, 12,036 patients were included in the analysis with 6,018/group. Mean age was 75 years and 50% were male. While controlling for differences in baseline characteristics using PSM, patients who initiated with SU had a significantly (p<0.001) higher incidence of insulin addition (2.8% vs. 1.4%) compared to those initiated with MET after 1 year of follow up. The likelihood of add-on insulin use was higher in patients initiated with SU than with MET (OR [95% CI] = 1.96 [1.51, 2.55]; p<0.001). SU was also significantly associated with shorter time to insulin add-on use compared to MET (HR [95% CI] = 2.20 [1.91, 2.52]; p<0.001). The rate of insulin addition remained significantly higher (p<0.001) with initial SU monotherapy vs. MET after 2 and 3 yrs of follow up (6.1% vs. 2.6%, and 8.1% vs. 3.9%, respectively). **CONCLUSIONS:** In a cohort of older patients with T2DM initiating antihyperglycemic therapy, patients who started with SU monotherapy received insulin therapy more frequently and earlier than those who started with MET.

PDB16

TREATED TO GLYCEMIC CONTROL TARGET ASSESSED BY FASTING PLASMA GLUCOSE (FPG) AND GLYCATED HEMOGLOBIN (HBA1C) IN PATIENTS WITH TYPE II DIABETES

Li Q[1], Bouchard JR[2], Wu N[1], Boulanger L[1]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Novo Nordisk, Inc., Princeton, NJ, USA*

OBJECTIVES: This study evaluated glycemic control after basal insulin initiation among patients with type II diabetes mellitus (T2DM). **METHODS:** A retrospective analysis was conducted using electronic medical records (EMR) from General Electric (GE) health care. Adult patients with T2DM who initiated basal insulin between February 2006 and August 2009 were selected, and the date of insulin initiation was set as the index date. The proportion of patients reaching fasting plasma glucose (FPG) target (FPG between 70-130 mg/dL) and glycated hemoglobin (HbA1c) target (HbA1c<7%) were reported. Time to reaching FPG and HbA1c targets was assessed, and Cox proportional hazard models were established to identify associated demographic and clinical factors. **RESULTS:** A total of 1473 patients (mean age 63.0 years; 51.3% female) were identified. Of them, 12% had baseline HbA1c ≤ 6.5, 7% had 6.5 < HbA1c ≤ 7, 23% had 7 < HbA1c ≤ 8, 21% had 8 < HbA1c ≤ 9, and 37% had HbA1c > 9. A higher proportion of patients reached the FPG target than the HbA1c target (52% vs. 45%) 12 months after insulin initiation. Patients reached the FPG target (median: 337 days, 95% confidence interval [CI]: 308-366) sooner than the HbA1c target (median: 490 days, 95% CI: 400-587). There was a greater variation in time to reaching the HbA1c target than the FPG target across groups of patients with different baseline HbA1c values. Baseline HbA1c level was the main factor influencing the time to reaching FPG or HbA1c target, with higher baseline HbA1c values associated with longer time to glycemic goal. **CONCLUSIONS:** About half of the patients with T2DM reached the glycemic goal after initiating basal insulin. Patients reached the FPG target sooner than the HbA1c target.

PDB17

USING A NOVEL, GRAPHICAL METHOD TO ANALYZE COMPLEX TREATMENT PATTERNS FOR PATIENTS WITH ACROMEGALY

Broder M[1], Liu Z[2], Cherepanov D[1], Neary MP[2], Chang E[1]
[1]*Partnership for Health Analytic Research, LLC, Beverly Hills, CA, USA,* [2]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA*

OBJECTIVES: Acromegaly is a rare, slowly progressing disorder resulting from excessive growth hormone. It is characterized by skeletal and soft-tissue enlargement and increased risk of cardiovascular death. Treatment may be long-term and complex, involving medications, surgery, and radiotherapy; and there are limited published data on treatment patterns. We used a novel graphical technique to analyze treatment patterns in acromegaly. **METHODS:** Combining two major US claims datasets (Thomson Reuters MarketScan and IMS Health PharMetrics), we identified acromegaly patients first treated between July 1, 2002-December 31, 2009. Patients were followed for 6 months to 3 years, from first treatment until either end of enrollment or 6/30/10. We analyzed treatment patterns using an innovative method which produces high-resolution images combining thousands of individual patient histories. These images used multi-colored line segments to represent different treatments. Images were reviewed for segment length and changes in colors to evaluate treatment patterns over time. We compared graphical results to summary statistics. **RESULTS:** We identified 2,027 newly treated acromegaly patients. First observed treatment was surgery in 733 patients (36.2%), pharmacologic therapy in 1203 (59.3%) and radiation in 91 (4.5%). Octreotide acetate long-acting (LAR) for injection was the first treatment in 173 patients (8.5%). Most users initiated therapy at 10-20mg/month (n=141, 81.5%). Among these, 47 (33.3%) increased octreotide dose or switched to other treatments in the follow-up period. Second treatment was octreotide 30mg/month in 39 (83.0%), 40mg/month in 7 (14.9%), and surgery in 1 (2.1%). Graphical analysis revealed patterns of treatment switching and medication persistence that differed depending on the initial therapy; multiple images from this analysis will be presented. **CONCLUSIONS:** Invasive treatments appeared less common than pharmacologic therapy as initial acromegaly treatments. Most octreotide LAR for injection users remained on their initial therapy without dose or treatment changes during observation. Graphical analysis provided detailed insights not immediately apparent in summary statistics.

PDB18

VALIDATION OF A DIABETES MODELING FRAMEWORK

Furiak N, Bansal M, Gahn JC, Klein RW, Smolen HJ
Medical Decision Modeling Inc., Indianapolis, IN, USA

OBJECTIVES: To validate outcomes from a diabetes model through comparison to results reported in trials published in the peer-reviewed literature. **METHODS:** Diabetes is a debilitating, costly disease that continues to increase in prevalence. Computer simulation models that estimate the impact of interventions on behalf of patients with diabetes are pivotal tools in improving care and evaluating place in therapy and cost-effectiveness of new treatments. The model was developed using the latest, best available evidence from the literature. It includes a set of complication submodels, a continuous-time HbA1c model, and a treatment model that can replicate recently published consensus algorithms. Additionally, the model incorporates treatment specific adverse events, patient adherence to therapy, and estimates of the patient population with a durable response. Random sampling from distributions from trial cohort characteristics is performed to build a patient profile. Each patient is simulated over the trial timeframe. Complications included: macrovascular-heart (coronary heart disease+congestive heart failure), microvascular-stroke, microvascular (renal+neuropathy+retinopathy), mortality, and overall complications rates. Scatter plots of the model predicted results versus the results reported for numerous trial populations in the literature (including 7 studies from ACCORD, ASPEN, and ADVANCE) were constructed. Linear regression estimates were calculated with adjusted correlation coefficients as an estimate of model validity. **RESULTS:** The predicted model outcomes were generally acceptably accurate as judged by adjusted correlation coefficients (macrovascular-heart, 0.9118; macrovascular-stroke, 0.5388; microvascular, 0.9508; mortality, 0.9808; overall complications, 0.9334). **CONCLUSIONS:** The diabetes modeling framework possesses the necessary flexibility to perform broad population analysis and important subgroup analyses. The validation exercise, in which the model simulates published cohorts, adequately predicts observed rates of complications.